THE CLINICAL INVESTIGATOR AS AN ENDANGERED SPECIES*

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The title of this symposium is "The Academic Physician: An Endangered Species." There is a paradox in that title. The paradox is that we have never had more full-time physicians in academic medicine than we have right now. About 33,000 physicians have full-time faculty positions in the United States, and that is close to 10% of the physicians in this country. This large figure reflects the expanding clinical roles of academic medical centers, which include, for example, 25% of all acute and intensive care beds of the country. Annual Association of American Medical Colleges surveys of funded, unfilled faculty vacancies have listed about 1,000 available positions each year over the last 10 or 15 years. Each year faculty ranks grow by 1,000, but another 1,000 new positions become available to be filled the following year. Thus, in the global sense there continues to be a shortage of academic physicians. But these position vacancies tend to be concentrated in specific fields, such as anesthesiology and pathology, with high service requirements. These are not the endangered species that I am referring to.

Eighteen months ago, as part of a presidential address, I discussed this topic with respect to the *clinical investigator* with special emphasis on the *physician-scientist*.[1] I use that term to signify an individual thoroughly trained in clinical medicine and *also* thoroughly trained in a scientific discipline, and who, in addition, participates in both clinical and experimental endeavors as a career role. Thus I refer to the physician who is simultaneously a serious scientist, and far less to the clinician who may occasionally also do some research. I want to discuss the topic in that

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restricted sense once again, for I continue to believe that there is now a short supply and an impending scarcity of dedicated physician investigators, and that they are essential to the orderly introduction of scientific advance into clinical practice. First, I shall briefly review the training vehicles by which such individuals have been launched in recent years.

The *training grant* is the vehicle primarily responsible for the development of academic physicians. It emerged during the mid-1950s from the National Institutes of Health. At that time its stated purposes included not only the development of researchers but the training of clinicians to practice in specialties that were then underrepresented, such as cardiovascular disease and gastroenterology. A training grant is an award to an institution, usually to a department or one of its divisions, to support training in a specific discipline. The award contains stipend support for a specified number of trainees, plus some support for the training program, such as partial salaries for key personnel directing the training and funds for equipment and supplies needed in research training.

A second vehicle of support is the direct fellowship, an award made to an individual to support his training in a specific laboratory under a specific mentor. A fellowship application requires a detailed description of the research to be done during training, and therefore tends to be available only to persons with some preliminary laboratory experience and a fairly well formulated research training plan. This award also provides stipend support plus a small sum for supplies, but does not provide support for the institution. The combination of training grants that enable a person to initiate research training in a good environment and fellowships that enable a somewhat more advanced trainee to work with a specific outstanding investigator has produced a steady supply of physician investigators as well as of more fundamental scientists.

The policy of excluding routine clinical training from training grants and of restricting support to research and academic clinical development began during the 1960s. Later, grants came under attack by the executive branch during the Nixon administration, which viewed research training as a personal equity that ought to be financed by the recipient. Training grants and fellowships were summarily discontinued in 1973. Months later, after several landmark court cases, impounded funds were released to complete outstanding commitments, but still no new awards were authorized. However, Congress was persuaded of the essential role of federal stipend support in producing the investigators needed to meet our national goals in

health research, for example, in the "war against cancer." In July 1974 Congress passed the National Research Act, which authorized National Research Service Awards, reinstating training grants and fellowships on July 1, 1975. There were, however, several stringent new conditions. Notable among these was a provision that trainees who accepted federal support but who did not subsequently engage in research or academic work were to repay the federal government through service in underserved areas or through repayment of the stipend. Another provision of the Act required the National Academy of Sciences to conduct a continuing study to establish the nation's overall needs for biomedical and behavioral research training and to report annually on the subject areas in which this research training was needed, the number of researchers needed in each area, and the extent of training that should be provided.

The important word in the charge was "need," which is very difficult to define. Because the federal government is the chief purchaser of biomedical research, the definition of need for investigators involves an assumption concerning the biomedical research budget three to eight years in the future. In the absence of firm data on the need for clinical investigators, the committee assumed a steady state in the federal research budget with annual inflation indexed increased only, and assumed that two thirds of old style traineeships and fellowships were held by physicians with genuine research and academic interests. There had been 4,200 such trainees per year in postdoctoral training positions prior to this Act. The committee therefore recommended that 2,800 such positions be offered annually. Available traineeships and fellowships were to be limited to research training and academic development. Only such clinical training as was necessary to produce an investigator-teacher was to be included.

Examination of federally supported training under these new conditions during the past several years has revealed some rather surprising data. The sum of funded postdoctoral trainees and fellows in clinical research fell far short of the 2,800 recommended positions. Some of the constraints have been budgetary, but the overriding factor has been a shortage of M.D. applicants for available traineeships and fellowships. For example, in 1977 the Academy Committee found that only 2,304 of the authorized 2,800 positions had been filled; thus, almost 500 authorized positions were not awarded. Moreover, of the 2,304 positions awarded,only 1,843 were filled by holders of medical or dental degrees. Thus, 460 positions, or 20% of *clinical* traineeships and fellowships were filled not by M.D. but by Ph.D.

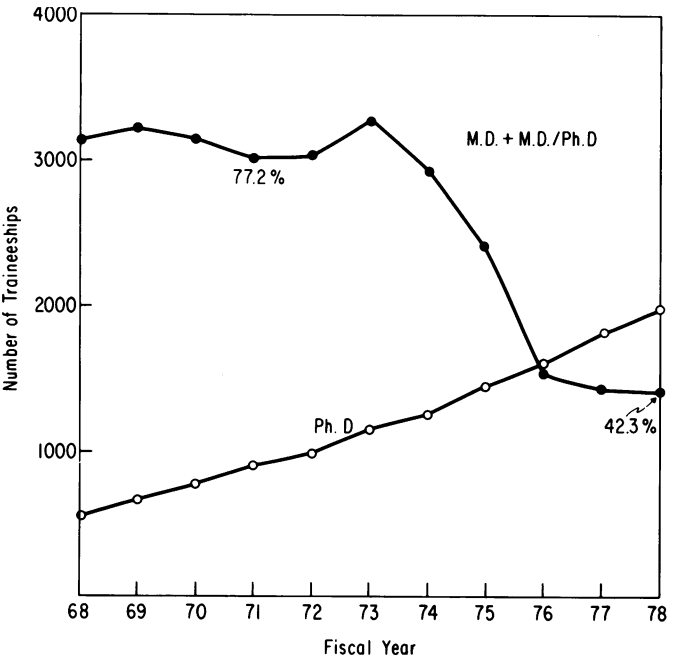

Fig. 1. Postdoctoral traineeship awards — N.I.H.

trainees. These figures describe both a striking decline of interest in clinical investigation by young physicians and a growing substitution of M.D. investigators by Ph.D. scientists. We shall return to this topic later.

Figure 1 shows the number of postdoctoral trainees supported by National Institutes of Health training grants during the last decade. Note the precipitous decline in postdoctoral traineeships awarded to physicians beginning about 1974, from around 3,200 per year to about 1,400 per year. A substantial component of this decline is thought to reflect the discontinuation of clinical training under National Institutes of Health auspices, but the decline is far greater than we would have anticipated if that were the only new factor. These data may indicate that the Academy's estimate that two thirds of the original trainees were interested in research and academic careers too high. Perhaps a larger fraction of trainees than estimated had predominantly clinical practice goals, following completion of a few research projects. This fraction has now found alternative support through clinical specialty residencies offered by the Veterans Administration. By contrast, postdoctoral training awards to Ph.D.s have been increasing throughout the decade. The Ph.D. group probably contains fewer in-

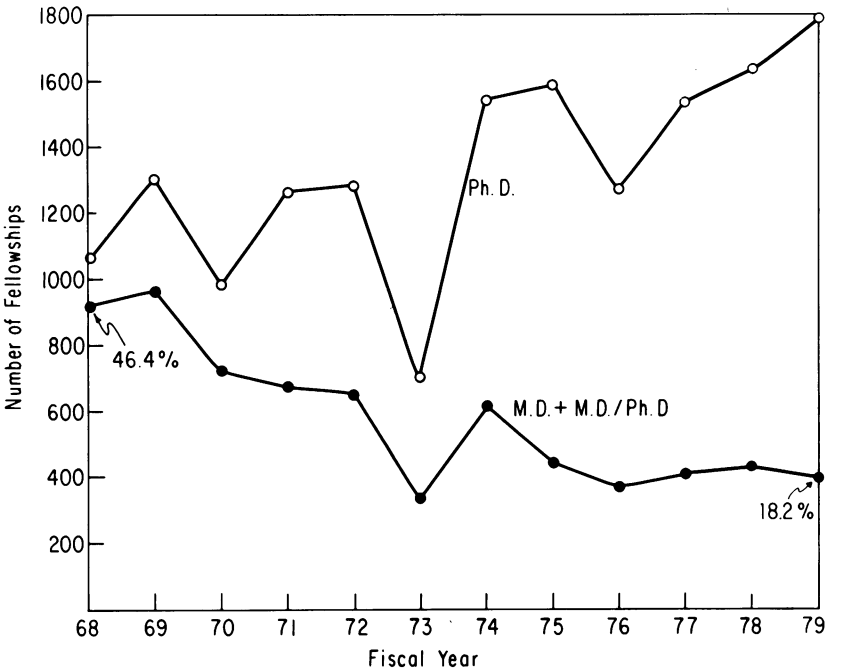

Fig. 2. Postdoctoral research fellowship awards — N.I.H.

dividuals with ambiguous objectives. In the last year for which figures are available, 1978, only 42% of traineeships were awarded to holders of M.D. degrees. This figure contrasts with 86% in 1968 and 77% in 1971.

Research fellowships, which, as mentioned above, depend on the presentation of a research plan and a proposal to work under the guidance of a particular scientist, select out more experienced and more strongly committed applicants than are found, on the average, in the traineeship group. Figure 2 shows that there has also been a continuing decline in the number of direct fellowships awarded to M.D. and M.D.-Ph.D. investigators, from about 900 a year in 1968 to 400 in 1977. The gradual increase in the number of such awards made to Ph.D. postdoctoral fellows during the same period of time may also be noted.

The percentage of postdoctoral fellowships awarded to physicians declined from about 46% of the total in 1968 to just over 18% in 1979. The decline in awards made to physicians began about five years before the redefinition of the traineeships and fellowships in 1974. The conclusion seems inescapable that substantially fewer physicians undertake research fellowship training today than a decade ago. The decline antedates the attack on the training

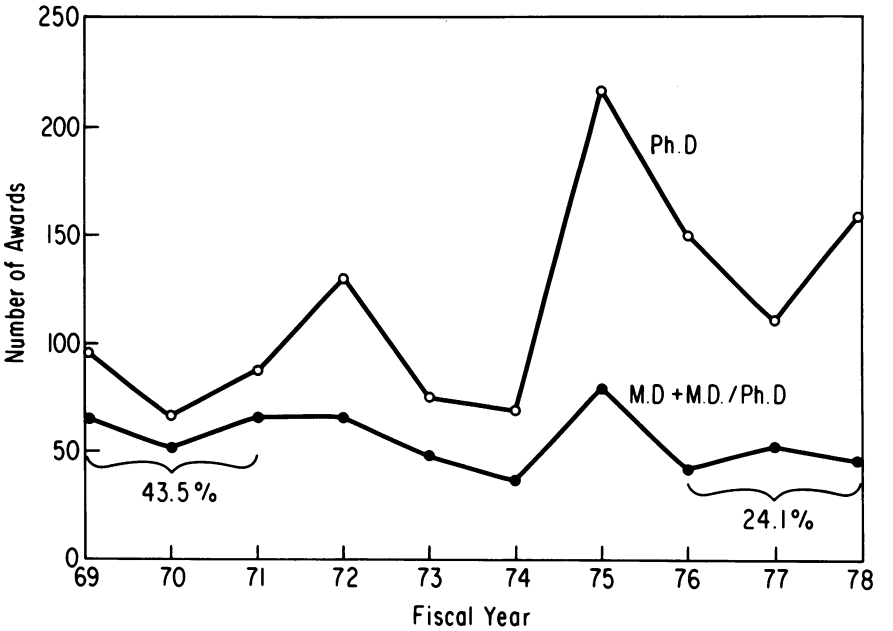

Fig. 3. Research career development awards — N.I.H. Reproduced by permission from Wyngaarden, J.B.: The clinical investigator as an endangered species. *N. Engl. J. Med. 301:* 1254, 1979.

programs by the Nixon administration, and probably reflects a more long-standing trend.

Figure 3 shows that there has also been a slight decline in the number of M.D.s and M.D.-Ph.D.s qualifying for research career development awards by the National Institutes of Health in the past 10 years. The decline is more striking when expressed as a percentage of total awards made. While M.D. applicants were losing some ground, Ph.D. applicants were making substantial gains: M.D. award holders declined from 43% of the total to about 24% of the total during the decade.

In 1971 the National Institutes of Health introduced young investigator awards for research-oriented faculty members three to seven years past the receipt of their doctoral degrees. These junior faculty awards in specific disciplines usually follow postdoctoral traineeships or fellowships, and usually occur before a recipient is qualified for a research career development award. This program has grown significantly after a modest start (Figure 4). More than 240 awards were made in 1978. Initially, the majority of these awards went to holders of clinical degrees. During the last three years, the number of Ph.D. recipients has been greater than the number of M.D. recipients. As one compares the success rate of applicants for these awards (Figure 5) one sees that the M.D. professional degree holders have

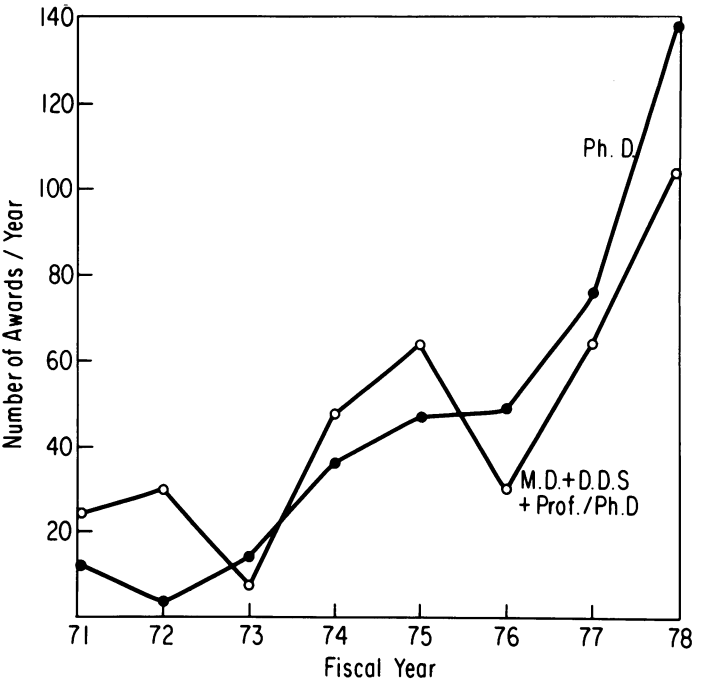

Fig. 4. Young investigator awards — N.I.H. (R23, K07, K08). Reproduced by permission from Wyngaarden, J.B.: The clinical investigator as an endangered species. *N. Engl. J. Med. 301:* 1254, 1979.

slipped a little compared to Ph.D. holders in the last two years, but in general the figures are comparable.

The final subtopic of this analysis deals with the doctoral degree held by new principal investigators receiving their first research grant awards. Figure 6 shows that in 1966 more than 41% of research grants awarded to new principal investigators were made to M.D. scientists. This figure then declined for almost a decade to a low of 18% in 1975. The percentage improved somewhat during the next two years but in 1978 was again less than 20%. If the principal investigators with both M.D. and Ph.D. degrees are included, the figures are slightly better—43, 22, and 25%, respectively. By contrast, the percentage of new investigators holding Ph.D. degrees has risen from just under 50% in 1966 to about 70% in recent years.

During the years represented by these figures, the absolute number of research grants awarded to new M.D. applicants has not changed very much (Figure 7). An average of about 300 awards per year has been made to holders of M.D. degrees throughout this period. By contrast, the number of awards made to Ph.D. degree holders has approximately doubled during the same decade. These data indicate a major shift in the balance of

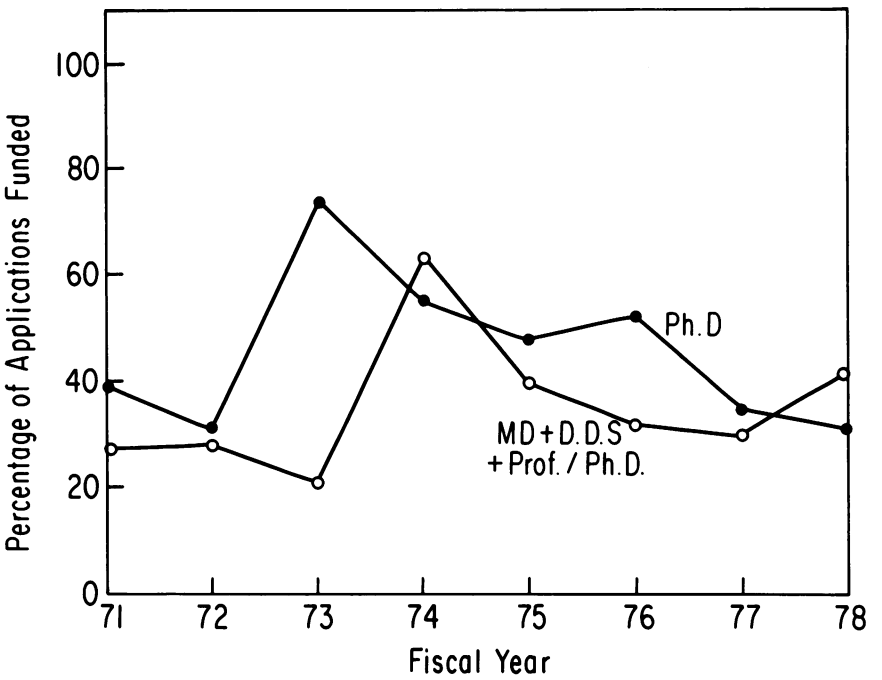

Fig. 5. Young investigator awards — N.I.H. (R23, K07, K08). Reproduced by permission from Wyngaarden, J.B.: The clinical investigator as an endangered species. *N. Engl. J. Med. 301:* 1254, 1979.

research support between clinical research and more basic biological research. This is not the result of planning or of high level research policy decisions. Rather, it reflects the growing scarcity of well-trained physician investigators.

One indication of this is the success rate of applicants for research grants from the National Institutes of Health. The percentage of submitted requests approved and funded has been approximately the same for M.D. and Ph.D. applicants (Figure 8). Variations over the decade have been comparable in the two groups. That the number of research grants awarded to M.D. investigators has not declined very much and that the success rates of M.D. applicants remain equal to those of Ph.D. applicants has suggested to some that there is in reality no valid basis for concern about the supply of clinical investigators. But this interpretation is deceptive. It ignores the great shift in balance between M.D. and Ph.D. investigators, and fails to appreciate the age lag between the physicians who qualify for a direct research award and those about to enter research training. *It is the progressive decline in the number of new entries that constitutes the danger to the survival of the species in the numbers and quality needed to maximize*

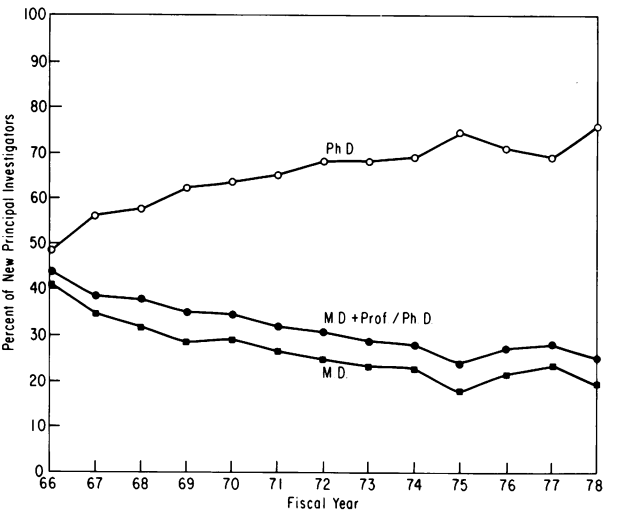

Fig. 6.New principal investigators on N.I.H. research projects. Reproduced by permission from Wyngaarden, J.B.: The clinical investigator as an endangered species. *N. Engl. J. Med. 301:* 1254, 1979.

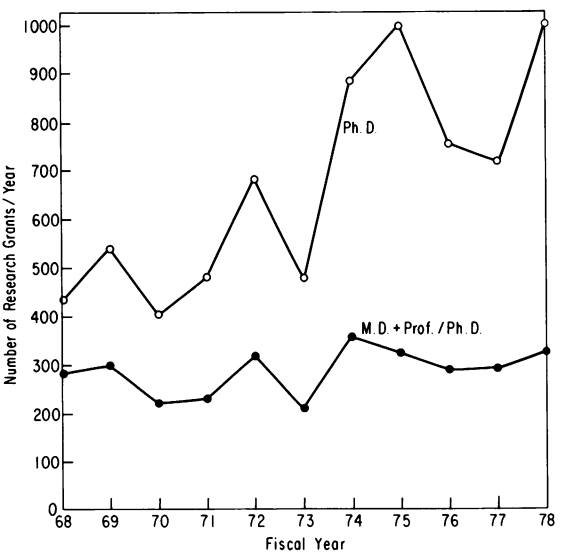

Fig. 7. Research grants awarded to new principal investigators by earned degree. Reproduced by permission from Wyngaarden, J.B.: The clinical investigator as an endangered species. *N. Engl. J. Med. 301:* 1254, 1979.

the rate of progress against the serious diseases of mankind.

But another point I want to make is that these trend data also contain the basis for valid encouragement of the young physician contemplating a research-oriented academic career. With respect to young investigator awards and new principal investigator research grant applications, *the data*

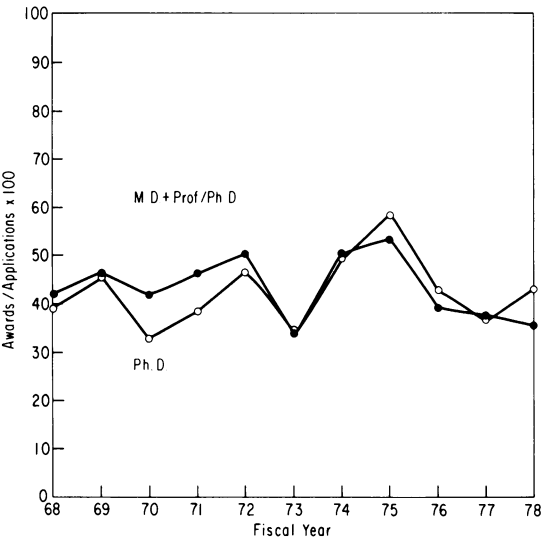

Fig. 8. Percentage success of new N.I.H. research applicants by degree of principal investigator.

show no decline in the success rate of those M.D. applicants who have sought support over the last decade. This point deserves special emphasis. It should be a matter of great encouragment to medical students, residents, and fellows that the success rate for those who do apply both for support as young faculty members and as principal investigators on research grants remains as high as it has been for the past decade.

The reasons for the decline in research interests among young physicians are complex. In an earlier publication,[1] based on an address given in May 1979, I discussed several: a reevaluation of goals in the wake of the Vietnam conflict by the young, leading to greater emphasis upon primary care and family medicine, and reduced interest in biomedical research; economic factors, including an expanding average debt load upon graduation, increasing costs of living, and the seductive lure of lucrative practice and the extraordinary incomes that can be made in procedure-based specialty medicine; curriculum revisions that have largely eliminated laboratory-based experience from basic science courses except for anatomy; the ever increasing "sophistication-factor" of modern biomedical research, which translates into requirements for extensive scientific training of medical students and residents who wish to prepare for research-oriented careers; instability of federal support for biological research and training, and the perception of increasingly intense competition for funding at junior faculty

levels; the payback provision of the National Research Service Awards, which intimidates young physicians not yet confident of their ability to succeed in a new venture; and the growth of specialty and subspecialty certifying boards, with a resulting lengthening of required residency and clinical fellowship training.

In the intervening year and one half, several developments have converged to brighten the outlook somewhat for the young physician contemplating a research career. Emphasis upon primary care and family medicine has stabilized, the call for increased production of practicing physicians has been muted, and the pendulum of interest in research-oriented academic medicine have begun to swing back. Stipend levels of traineeships and fellowships has been improved to parity with residency salaries. In addition, several private associations and foundations have launched clinical investigator or young faculty development programs with substantial salary support, although the total of such awards is still small. Faculty salaries, particularly in Veterans Administration Hospitals, have been increased. The National Institutes of Health has increased by about 10% the number of entry positions into M.D.-Ph.D. training program. The National Institutes of Health has obtained approval to stabilize the number of new research grant awards at 5,000 per year. There is discussion in Congress of exempting the first year of supported training from payback obligation, although this has not yet happened, and experience has shown that only about 1% of those who accepted support have been required to repay it through service or rebate. The American Board of Internal Medicine has liberalized its Plan C, and no longer requires that an applicant with less than the standard number of years of formal residency or clinical fellowship training hold a full-time faculty position before being allowed to take the board examination.

Concern over the future availability of an adequate number of well-trained physician-investigators is becoming more general. The Committee on Biomedical and Behavioral Research Personnel of the National Academy of Sciences has accorded this topic its highest priority.[2] The Center for Policy Study of the University of Chicago convened a conference on "Clinical Research: Elements for a Prognosis" in June 1979.[3] Various subspecialty societies are addressing the problem as well.

One development that seems to be underway is the progressive replacement of M.D. investigators by Ph.D. scientists in clinical research. I have already commented on this with respect to training slots in clinical traineeships and fellowships. It is also occurring at more advanced levels,

such as semipermanent appointments as research associates or research assistant professors. This trend is related to many factors: the relative unavailability of well-trained physician scientists to fill these positions; the supply of Ph.D. scientists has run ahead of faculty level academic and research positions in the basic biomedical sciences, with consequent expansion of the postdoctoral fellowship and research associateship pools, and an employment pressure to seek out new areas; the sophistication factor mentioned above has made investigators with Ph.D. training particularly valuable team members for physician scientists; and the salary levels for Ph.D.s in clinical research often run ahead of salaries in basic science departments. Most observers of the present scene predict that in the future the ranks of medical research will be filled increasingly by scientists who are not medically trained. Whether this will be beneficial to the progress of clinical research depends on the degree to which medically trained investigators are willing to secure the training necessary to become coequal professionals and to direct the course of the research program. This paper is addressed to the need for such professional scientists within the ranks of physicians. The problems of clinical research will not be solved by amateur M.D. investigators employing Ph.D. investigators. Nor will the pressing problems of disease be solved by investigators who lack a clinical background. What is needed, and what in my view in now seriously endangered, is an adequate supply of physician investigators, thoroughly trained in a scientific discipline as well as in a clinical field of medicine, capable of bringing both their medical insights and their scientific skills to biomedical science.

ACKNOWLEDGEMENT

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